Cochlear Implant Patients and Meningitis

(Excerpted from an FDA Public Health Web Notification of August 15, 2002)

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The FDA has recently sent out a notification regarding a possible association between cochlear implants and the occurrence of bacterial meningitis. The cause of meningitis in these patients has not been established as yet.

Within the past 14 years, 52 cases of meningitis have been reported worldwide to manufacturers of cochlear implant devices. These have occurred in children and adults ranging in age from 21 months to 72 years, who have undergone cochlear implantation for severe to profound deafness. Twelve deaths have resulted within these cases.

Although CSF culture results were not available for all cases, most have been caused by pneumococcus, with other organisms involved including Hemophilus influenza (Hib), Strep. viridans, enterococcus and *E. coli*. For 6 cases with pneumococcus meningitis and a vaccination history available, none had been vaccinated. Most of the patients have been children under the age of five years.

While the cause of meningitis in these cochlear implant recipients is not yet clear, investigations are underway to try to obtain more information. Some deaf patients may have congenital abnormalities of the cochlea, which predispose them to meningitis even prior to implantation. Because the cochlear implant is a foreign body, it may act as a nidus for infection when patients have bacterial illnesses.

Vaccination Issues: ***Cochlear implant candidates, as well as those with implants, may benefit from vaccinations against organisms that commonly cause bacterial meningitis, particularly pneumococcus and Hib.*** Immunization status should be determined for all implant candidates prior to surgery, and also for those with an existing implant.

Hib conjugate vaccine is recommended for all children up to age five years. Pneumococcal conjugate vaccine is recommended for all children less than age 2 years, and for children up to age five years at high risk of invasive disease *(which now appears to include cochlear implant patients)*. The 23-valent pneumococcal polysaccharide vaccines are recommended for children over age two years, adolescents, and adults at high risk of invasive pneumococcal disease.

For children age two to five years who are at high risk of invasive pneumococcal infections, the pneumococcal conjugate vaccine, followed at least two months later by the 23-valent polysaccharide vaccine, is recommended in order to provide protection against a broader range of serotypes.

Reporting of cases of meningitis in cochlear implant recipients is encouraged. Cases can be reported directly to the device manufacturer or to MedWatch, the FDA's voluntary reporting program. Report online at http://www.accessdata.fda.gov/scripts/medwatch/; by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, FDA, HF-2, 5600 Fishers Lane, Rockville, MD 20857.